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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,298	12/21/2001	Toshihiko Yanagita	YAM 2 0014	9018

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,298	YANAGITA, TOSHIHIKO	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed, 7-22-05 is hereby acknowledged. Claims 1-2 were amended and claim 18 was added. Claims 1-15 and 18 are pending in this application.

2. All rejections made in the previous office action and not cited herein are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1, 7-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sameulson et al.

The claims are drawn to method of preventing premature labor or miscarriage using a composition comprising adrenomedullin that has several amino acid deletions.

Applicants argue that the claims are intended to capture only those analogs which may match the claimed amino acid sequences after specific amino acid substitutions, not any amino acids substitution. Specifically, Applicants intend only conservative substitution.

Applicatns arguments have been considered but not found persuasive.

First, the claims do not recite that only conservative substitutions are intended within the means of the claims. Thus any substitution is proper. Further, n page 10 of the specification, it is stated "AM is used in the present invention is not necessarily limited to the above-described

sequences, but includes, as subjects, homologous peptides having an amino acid sequence having one or several amino acid deleted, substituted, or added in the above-described sequences and maintaining a desired activity. Amino acid conservative substitution is one preferable means for obtaining homologous peptides." Thus, amino acid conservative substation is only a "one perferrable means" and not the only means. The broad definition allows for any substitution, deletion or addition. Sameulson et al. teach calcitonin gene related peptide (CGRP) and its usefulness in inhibiting spontaneous contraction (see abstract). The reference states that CGRP is a potent inhibitor of spontaneous contractile activity in the oviduct and uterus (see page 229). CGRP reads on the claimed invention because CGRP is a deletion analog of adrenomedullin. Since the claims allows for "several amino acid" deletions, CGRP meets the limitation of claims. Note that CGRP is a AM homolog.

Rejection is maintained.

New Ground For Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite that the aderenomedullin is administered without administering CGRP and "caused by an inflammatory mediator.". This, amendment, constitutes new matter.

The MPEP states that when an amendment is made to the claims, "Applicant should also specifically point out the support for any amendments made to the disclosure." MPEP 714.02 and 2163.06. In their response, did not provide specific support for the claimed invention.

Lack of Literal support

For the exclusion of CGRP, the specification does not provide any support that aderenomedullin (AM) is to administered alone without combining CGRP. Attention is directed to page 25 which discusses the CGRP receptor. Even through the discussion on this page, the originally filed specification does literally state that CGRP is specifically excluded, as agent to be administered, within the spirit of the invention.

For contraction caused by an inflammatory mediator, the specification lacks any literal support. When the specification discusses myomaterial contractions it is always in the context of bradykinin induced contractions (see page 16, 26 for example). The specification does not literally provide support for contractions "caused by inflammatory mediator."

Lack of Inherent Support

It is acknowledged that support for a claimed limitation need not be in *ipsis verbis* to be sufficient. Support can be provided by inherent or implicit support. However, the instant specification lacks any inherent or implicit support to specifically exclude the administration of CGRP or that AM can be to treat any contraction caused by an inflammatory mediator. On page 25 of the specification, it is disclosed that the Activity of AM is blocked by CGRP [8-37]. Thus, one

could conclude that this peptide is excluded form the scope. However, the specification fails to address any issues with respect to CGRP. Reading the specification as a whole, one cannot conclude that CGRP is implicitly excluded form the scope of the claim.

With respect the inflammatory mediator, the attention is directed to page 24 of the specification. It is stated that "AM inhibited bradykinin-induced contractions, but had not effect on contractions induced by oxytocin or PGF2a or contractions caused by high K stimulus." It is known in the art that PGF2a is a inflammatory mediator. Thus, it is clear that not all inflammatory mediators are intended to be encompassed by the claimed invention. Accordingly, the specification lacks implicit support for this amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to recite contractions "caused by inflammatory mediator." It is unclear as to the exact definition of inflammatory mediator. The claims exemplifies bradykinin as the inflammatory mediator. However, the specification is silent on other agents that qualify as inflammatory mediators.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

10/3/06

Anish Gupta
Patent Examiner